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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,602

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Scott Hugh Miller

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EXAMINER

GEDEON, BRIAN T

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/595,602	<b>Applicant(s)</b> MILLER ET AL.	
	<b>Examiner</b> Brian T. Gedeon	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 15-26 is/are rejected.
- 7) ☒ Claim(s) 11-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of Applicant's claim for priority under 37 C.F.R. 371 as a national stage entry of PCT/AU04/01484. The date for priority has been determined to be 28 October 2004.

### ***Response to Amendment***

2. The preliminary amendment submitted 28 April 2006 has been acknowledged.

### ***Information Disclosure Statement***

3. The information disclosure statement filed 28 April 2006 has been accepted.

### ***Drawings***

4. The drawings filed 28 April 2006 have been approved.

### ***Specification***

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

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6. Claim 4 is objected to because of the following informalities: a typographical error appears to exist in line 3, wherein a "the" has been inserted between sandwiching and between. Appropriate correction is required.

7. Claim 6 is objected to because of the following informalities: claim 6 in line 1 fails to further limit the "vessel deformer" as in the claim it depends on. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, 13-15, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are considered indefinite because First, it is indefinite as to what point of reference the sides and ends are defined with respect to each other. Second, is indefinite as to what point of reference is used to define the center in relation to the sides (i.e., where is the center located, e.g., the axial center). Third, the claim recites contradictory limitations with the recitation of "at, near, or along." The scope of these terms presents a range of a narrow limitation to a broad limitation. Fourth, it is indefinite with regard as to how the less compressive force can be applied to "at least some of its sides" when the claim states that there are only two sides.

Further in regard to claims 1 and 3, it is indefinite what structural elements of the construction allow certain parts of the warp to exhibit more elastic/stretchable properties that allow it to use less compressive force.

Further in regard to claim 2, it is indefinite how the loss of aortic compliance can be both minimized or enhanced due to the non inelastic property.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-3 and 15-17 are rejected under 35 U.S.C. 102 (b) as being anticipated by Shifrin et al. (WO 95/05122).

In regard to claims 1 and 3, Shifrin et al. describe a band 3 for wrapping around a vein or other blood vessel, page 3 lines 17-19, wherein the band is made from a single length of material and has variable rigidity, page 3 lines 20-25. The band 3 has a main compressing portion, and is flexible, page 3 lines 28-33.

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In regard to claim 2, the band of Shifrin et al. is considered not inelastic due to its flexibility, and choice of construction materials, which allow it to have shape memory and a spring-like effect, page 3 lines 25-27.

In regard to claim 15, the band 3 is reinforced with a metal alloy wire which is considered to have a higher tensile strength than the rest of the materials in the band.

In regard to claims 16 and 17, the wrap of Shifrin et al. is comprised of material with variable rigidity and compression rates, page 3 lines 20-23.

12. Claims 1-3, 9, 10, 17, 22, and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilles et al. (US Publication no. 2006/0052866).

In regard to claims 1 and 3, Gilles et al. describe a method for treating a stiffened blood vessel by applying an elastic membrane wrap 6, formed of biocompatible material, and engages the blood vessel in such a manner as to reduce the diameter of the blood vessel, para 29-30.

In regard to claim 2, the wrap of Gilles et al. is not inelastic, para 99.

In regard to claims 9, 10, 17, and 26, the wrap of Gilles et al. is constructed out of knitted or woven material from biocompatible polymers, para 93.

In regard to claim 22, the wrap of Gilles et al. is shaped to allow for good conformance with an aorta, para 25-26.

In regard to claims 24 and 25, the wrap of Gilles et al. is constructed out of elastic silicon or elastic polyurethane material, para 42.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 4-8, 18-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shifrin et al. (WO 95/05122).

In regard to claims 4-8, Shifrin et al. describe the device as claimed, except do not explicitly teach that the wrap is adapted to secure a vessel deformer adjacent to the vessel. The Examiner considers that this feature would be obvious to one of ordinary skill in the art at the time the invention was made in view that the wrap is merely "adapted to" secure a vessel deformer, regardless of what type of deformer is preferred, which the Office interprets of only needing to be capable of performing, since it would only involve placing a vessel deformer adjacent the vessel, then wrapping the invention of Shifrin et al. around it.

In regard to claims 18-21, Shifrin et al. describe the device as claimed, except do not explicitly teach that the wrap has varying dimensions throughout. However, the Examiner considers that modifications to the wrap of Shifrin et al. would be obvious since it would not require undue experimentation or anything beyond routine skill in the art to implement, nor would such modifications lead to the destruction of the function of the Shifrin et al. wrap. Such modifications are considered matters of design choice.

In regard to claim 23, the wrap of Shifrin et al. has a cavity to allow for fluid or

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gas, page 3 lines 29-33, and thus an access port for inserting a fluid or gas would be obvious.

15. Claims 4-8 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilles et al. (US Publication no. 2006/0052866).

In regard to claims 4-8, Shifrin et al. describe the device as claimed, except do not explicitly teach that the wrap is adapted to secure a vessel deformer adjacent to the vessel. The Examiner considers that this feature would be obvious to one of ordinary skill in the art at the time the invention was made in view that the wrap is merely "adapted to" secure a vessel deformer, regardless of what type of deformer is preferred, which the Office interprets of only needing to be capable of performing, since it would only involve placing a vessel deformer adjacent the vessel, then wrapping the invention of Gilles et al. around it.

In regard to claims 18-21, Gilles et al. describe the device as claimed, except do not explicitly teach that the wrap has varying dimensions throughout. However, the Examiner considers that modifications to the wrap of Gilles et al. would be obvious since it would not require undue experimentation or anything beyond routine skill in the art to implement, nor would such modifications lead to the destruction of the function of the Gilles et al. wrap. Such modifications are considered matters of design choice.

***Allowable Subject Matter***



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16. Claims 11-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Freeman (US Patent no. 4,809,676) describes a heart assist device in the form of a blood vessel wrap.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/  
Supervisory Patent Examiner, Art Unit 3766

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12 October 2008